MEDICAL MUTUAL®

Drug Policy

Policy:	Multiple Sclerosis and Ulcerative Colitis – Zeposia Care Value Policy	Annual Review Date: 06/15/2023 Last Revised Date: 02/15/2024

OVERVIEW

Zeposia, a sphingosine 1-phosphate receptor modulator, is indicated for the following uses:[1]

- **Relapsing forms of multiple sclerosis**, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease in adults.
- **Ulcerative colitis**, in adults with moderately to severely active disease.

For more information on criteria within a Prior Authorization program by specific condition refer to the standard *Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy.*

Preferred and Non-Preferred Products.[¥]

	Multiple Sclerosis	Ulcerative Colitis
Step 1 **Preferred**	• generic glatiramer SC injection • generic dimethyl fumarate delayed-release capsules • generic fingolimod capsules • generic teriflunomide tablets	• Adalimumab Products[^] – Humira, Cyltezo/adalimumab-adbm, Hyrimoz, (NDCs starting with 61314)/adalimumab-adaz • Stelara SC
Step 2 **Non-Preferred** (directed to **ONE** Step 1 Product)	• Zeposia	--
Step 2 **Non-Preferred** (directed to **TWO** Step 1 Products)	--	• Zeposia

[¥] For Non-Preferred Adalimumab Products, refer to the *Inflammatory Conditions – Adalimumab Products Care Value Policy for National Preferred, High Performance, and Basic Formularies;* [^] A trial of more than one adalimumab product counts as ONE Preferred Product; SC – Subcutaneous.

POLICY STATEMENT

The Multiple Sclerosis Care Value Program has been developed to encourage the use of the Preferred Products. For all medications (Preferred and Non-Preferred) the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The Program also directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for 1 year. If a patient requesting a Non-Preferred Product meets the respective standard *Prior Authorization Policy* criteria but has not tried one Preferred Product, an offer to review for the Preferred Product(s) will be made.

The Inflammatory Conditions Care Value Program has been developed to encourage the use of the Preferred Products. For all medications, this program requires the patient to meet the respective standard *Prior Authorization Policy* criteria. Additionally, this program requires trial(s) of the Preferred Product(s) according to the table above, when clinically appropriate, prior to the approval of the Non-Preferred Products. There are also situations when trials of Non-Preferred Products will be considered; see criteria below. Other details of the program are as follows:

- **Continuation of Therapy:** Approval for a patient continuing therapy with a **Non-Preferred** (subcutaneous or oral) Product must be supported with verification, noted in the criteria as either **[verification in prescription claims history required]** or, if not available, as **[verification by prescriber required]**.
  - If the patient has at least 130 days of prescription claims history on file, claims history must support that the patient has received the Non-Preferred Product for the specified period of time (90 or 120 days) within a 130-day look-back period; OR
  - When 130 days of the patient's prescription claim history file is unavailable for verification, the prescriber must verify that the patient has been receiving the Non-Preferred Product for a specified period of time (90 or 120 days), AND that the patient has been receiving the Non-Preferred Product via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to the Non-Preferred Product).
  - For a patient continuing therapy, other conditions may also apply. Refer to criteria below.
  - **Approval Duration:** All approvals for continuation of therapy for Preferred and Non-Preferred Products are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Zeposia	**1. Multiple Sclerosis.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, iv, or v): **i.** Patient has been established on Zeposia for ≥ 120 days; OR **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND

	b) Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascensco ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **v.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **B)** If the patient meets the standard *Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product (dimethyl fumarate, glatiramer, fingolimod, or teriflunomide).

Zeposia	**2. <u>Ulcerative Colitis – Initial Therapy</u>.** **A)** Approve for 6 months if the patient meets the following (i <u>and</u> ii): i. Patient meets the standard *Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy* criteria; AND ii. Patient has tried BOTH an adalimumab product and Stelara subcutaneous. <u>Note</u>: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of an infliximab product (e.g., Remicade, biosimilars; Zymfentra) or Simponi subcutaneous, Entyvio intravenous or subcutaneous, Omvoh intravenous or subcutaneous, or Stelara intravenous also counts. **B)** If the patient has met criterion 2Ai (the standard *Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy* criteria), but criterion 2Aii is not met, offer to review for the Preferred Product (<u>adalimumab-adaz, adalimumab-adbm, Cyltezo, Hyrimoz (NDCs starting with 61314), or Stelara subcutaneous</u>) using the respective standard *Inflammatory Conditions Prior Authorization Policy* criteria. **3. <u>Ulcerative Colitis – Patient is Currently Receiving Zeposia</u>.** **A)** Approve for 1 year if the patient meets the following (i <u>and</u> ii): i. Patient meets the standard *Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy* criteria; AND ii. Patient meets ONE of the following conditions (a <u>or</u> b): a) Patient has tried BOTH an adalimumab product and Stelara subcutaneous; OR <u>Note</u>: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of an infliximab product (e.g., Remicade, biosimilars; Zymfentra), Simponi subcutaneous, Entyvio intravenous or subcutaneous, Omvoh intravenous or subcutaneous, or Stelara intravenous also counts. b) Patient has been established on Zeposia for at least 90 days <u>and</u> prescription claims history indicates <u>at least a 90-day supply of Zeposia was dispensed within the past 130 days</u> **[verification in prescription claims history required]** if claims history is not available, according to the prescriber **[verification by prescriber required]**. <u>Note</u>: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving <u>Zeposia</u> for at least 90 days AND the patient has been receiving <u>Zeposia</u> via paid claims (e.g., patient has <u>not</u> been receiving samples or coupons or other types of waivers in order to obtain access to <u>Zeposia</u>). **B)** If the patient has met criterion 3Ai (the standard *Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy* criteria but criterion 3Aii is not met, offer to review for a Preferred product (<u>Humira, adalimumab-adaz, adalimumab-adbm,</u>

	Cyltezo, Hyrimoz (NDCs starting with 61314), or Stelara subcutaneous) using the respective standard *Inflammatory Conditions Prior Authorization Policy* criteria.

REFERENCES
1. Zeposia® capsules [prescribing information]. Summit, NJ: Celgene; May 2021.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.